NOV 21 2000

SECTION II. SUMMARY AND CERTIFICATION

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

A. Device Name

Proprietary Name	PINNACLE® R/O II or RADIFOCUS® Introducer II
Classification Name	Introducer, Catheter
Common Name	Introducer Sheath

B. Intended Use

The PINNACLE R/O II is used to facilitate placing a catheter through the skin into a vein or artery. The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery. The RADIFOCUS Obturator is also an accessory device which is used by placing it into the sheath to create an occlusion and further provide support to the wall of the indwelling sheath while it remains in place within the vein or artery after removal of a catheter.

Note: This is the same intended use as the PINNACLE R/O, K984260.

C. Device Description

The PINNACLE R/O II is comprised of an introducer sheath and a dilator. The introducer sheath has a radiopaque marker that is highly visible under fluoroscopy. The marker is a band that is located approximately 5 mm from the sheath's tip.

The PINNACLE R/O II is used to facilitate placement of a catheter through the skin into a vein or artery. A Mini Guide Wire (with Inserter) may be included with PINNACLE R/O II. The Inserter does not contact blood and is used strictly for guiding the Guide Wire into a cannula or Introducer.

The Mini Guide Wire is inserted through a cannula placed in the patient's blood vessel. The PINNACLE R/O II is then inserted over the Mini Guide Wire and into the blood vessel. The Mini Guide Wire is then withdrawn from the vessel. The Dilator maintains the integrity of the Sheath and dilates the blood vessel while PINNACLE R/O II is being placed into the vessel. The Dilator can be removed and an appropriate catheter can then be inserted. The RADIFOCUS Obturator is an accessory device which creates an occlusion when inserted into the Sheath. The

Obturator also provides support to the indwelling Sheath after the catheter is removed.

The Sheath, Dilator and Obturator contain bismuth, making these devices slightly visible under fluoroscopy.

D. *Principle Of Operation / Technology*

The PINNACLE R/O II and its accessories are operated manually or by a manual process.

E. *Design / Materials*

Differences in materials between the PINNACLE R/O II and the PINNACLE R/O, K984260 raise no new issues of safety and effectiveness.

F. *Specifications*

Part	PINNACLE R/O II	PINNACLE R/O, K984260
Introducer Sheath Size Length	 6 – 8 French 5 – 110 cm	 4 – 11 French 5 – 110 cm
Dilator Length	 6 – 110 cm	 6 – 110 cm
Guide Wire OD	0.021" – 0.038"	0.021" – 0.038"

G. *Performance*

The PINNACLE R/O II is comprised of an introducer sheath with radiopaque marker and a dilator. Only the introducer sheath was modified. The dilator was not modified.

The following verification tests were performed to demonstrate the substantial equivalence of the modified device (PINNACLE R/O II) to the unmodified device (PINNACLE R/O).

- Kink Resistance
- Sheath-to-Housing Joint Strength
- Sheath Tip Penetration
- Sheath Tip Weld
- Radiopacity

None of the data raises any new issues of safety and effectiveness. Additionally, a risk analysis was conducted and there were no new issues of safety and effectiveness.

Therefore the performance of the PINNACLE R/O II is substantially equivalent to the performance of the PINNACLE R/O, cleared under K984260.

H. *Additional Safety Information*

Manufacturing controls include visual, functional, dimensional and sterility tests.

The PINNACLE R/O II is classified as an Externally Communicating Device, Circulating Blood, Prolonged Contact (24 hrs to 30 days). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". Results of the testing demonstrate that the blood contacting materials are biocompatible.

Sterilization conditions have been validated in accordance with ANSI / AAMI / ISO 11035-1994, *Medical Devices – Validation and routine control of ethylene oxide sterilization* and EN 550. The device is sterilized to a SAL of 10^{-6}.

I. Substantial Equivalence

The PINNACLE R/O II is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the PINNACLE R/O, cleared under K984260. Differences between the two devices do not raise any significant issues of safety or effectiveness.

J. Submitter Information

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Date Prepared: Oct. 30, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Ms. Yuk-Ting Lewis
Senior Regulatory Specialist
Terumo Medical Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K003424
Trade Name: PINNACLE® R/O II
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: October 30, 2000
Received: November 3, 2000

Dear Ms. Lewis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Note: This is the same intended use as the predicate device, K984260

510(k) Number (if known): _____

Device Name: PINNACLE R/O II

Indications For Use:

The PINNACLE R/O II is used to facilitate placing a catheter through the skin into a vein or artery. The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery. The RADIFOCUS Obturator is also an accessory device which is used by placing it into the sheath to create an occlusion and further provide support to the wall of the indwelling sheath while it remains in place within the vein or artery after removal of a catheter.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

K003424

(Optional Format 1-2-96)